

**BEST AVAILABLE COPY**

**WO0000235**

Publication Title:

**DISPOSABLE ABSORBENT ARTICLES WITH SKIN ADHESIVE**

Abstract:

Abstract of WO0000235

The present invention relates to disposable absorbent articles such as diapers, sanitary napkins and the like which are provided with adhesives for attachment of the article to the skin. In particular the present invention relates to adhesives which provide secure attachment and are pleasing to the skin upon application, yet cause no discomfort upon removal. This is achieved by selecting the chemical composition and rheological characteristics of the adhesives, particularly the viscous modulus  $G''$  in combination with the thickness  $C$  of the adhesive layer applied to the article for attachment to the skin. Data supplied from the esp@cenet database - Worldwide

-----  
Courtesy of <http://v3.espacenet.com>



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :  <b>A61L 15/58</b>		A1	(11) International Publication Number: <b>WO 00/00235</b>  (43) International Publication Date: <b>6 January 2000 (06.01.00)</b>
(21) International Application Number: <b>PCT/US99/12958</b>			(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: <b>11 June 1999 (11.06.99)</b>			
(30) Priority Data: <b>PCT/US98/13287 26 June 1998 (26.06.98) US</b>			
(71) Applicant (for all designated States except US): THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).			
(72) Inventors; and			
(75) Inventors/Applicants (for US only): D'ACCHIOLI, Vincenzo [IT/DE]; Parkstrasse 42, D-65779 Kelkheim am Taunus (DE). PALUMBO, Gianfranco [IT/DE]; Georgenfeld 7, D-61348 Bad Homburg (DE).			
(74) Agents: REED, T., David et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217-1087 (US).			

(54) Title: DISPOSABLE ABSORBENT ARTICLES WITH SKIN ADHESIVE

## (57) Abstract

The present invention relates to disposable absorbent articles such as diapers, sanitary napkins and the like which are provided with adhesives for attachment of the article to the skin. In particular the present invention relates to adhesives which provide secure attachment and are pleasing to the skin upon application, yet cause no discomfort upon removal. This is achieved by selecting the chemical composition and rheological characteristics of the adhesives, particularly the viscous modulus  $G''$  in combination with the thickness  $C$  of the adhesive layer applied to the article for attachment to the skin.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## DISPOSABLE ABSORBENT ARTICLES WITH SKIN ADHESIVE

Field of the Invention

The present invention relates to a disposable absorbent articles such as diapers, sanitary napkins, pantiliners, tampons, perspiration pads, adults incontinence devices and the like to be attached directly to the skin. The article utilises an improved adhesive having a specified rheology and application thickness in order to attach the article to the skin of the wearer so as to facilitate easy application and removal of the article from the wearer without pain, whilst ensuring maintenance of the article in the desired position, particularly on moist and wet skin for the entire period of wear, including circumstances or periods of wear during which the wearer is active, i.e. not bedridden.

Background of the Invention

Urine faecal management devices are known articles of manufacture that are designed to be worn principally by incontinence sufferers and in particular by bedridden patients. Such human waste management devices are attached to the natural anal region or artificial anus of the wearer and or the uro genital region and are intended to entrap and immediately contain faecal material and other bodily discharges.

Such devices as they are mostly known today are designed to be worn by bedridden patients. As such the devices are constituted of a relatively long and narrow tube, at one extremity of which there is an aperture and a skin attachment device upon which an adhesive can be applied.

Examples of these bags are disclosed for example in US 3,577,989, which details a disposable elimination-trapping bag for incontinence sufferers including a container member having an open-top portion, and a flange secured to the container member around the open-top portion. The flange may include a layer of adhesive on its surface as a means of attachment of the bag to the wearer or

alternatively discloses the use of elastic straps to attach the bag to the wearer. US 4,784,656 also describes a receptacle for collecting faecal matter from incontinence sufferers. The faecal collector comprises a gasket, conduit means or a cylinder and a receptacle; the receptacle and conduit means are each formed from two sheets of odour barrier thermoplastic film that are heat sealed along their side edges, respectively and the side surface of the gasket is coated with a layer of adhesive; GB 2 152 387, teaches a faecal collector for incontinence sufferers comprising a collection bag and a ring, which is provided with an adhesive. The faecal collector comprises a pair of panels of thermoplastic sheet material joined at their margins to define an elongate bag having an opening at one end. GB 1 078 588 describes a urine collector comprising a liquid proof bag of tube like configuration having an opening surrounded by an attachment means in the form of an adhesive material.

Other types of faecal management bags having a flatter shape are known from EP 245 064. EP 245 064 discloses bags having a front and a rear wall, the front wall containing the aperture and attachment means to the body. The attachment means is a skin compatible water resistant material such as a hydrocolloid and a water insoluble viscose elastic binder.

Due to their typical elongated shape and dimensions, such devices particularly when worn by active wearers, such as infants or non bedridden incontinent adults, can readily twist around the thighs of the wearers and/or can cause the formation of folds and kinks in the devices themselves. Under such circumstances the pressure and stress exerted upon the bag will naturally increase due to the movement of the wearer and the pressure of the wearer's body upon the bag. Consequently, the likelihood that the faecal material once excreted and contained within the bag will be caused to exert pressure upon the attachment means of the device will increase and as a result not only will the storage capacity of the device be detrimentally affected but also more importantly it may result in unintentional detachment of the device from the wearer during use. Such an occurrence is unacceptable causing distressing consequences for both the wearer and the carer.

Hence, it is critical that the urine and/or faecal management devices are designed such that they are securely attached to the skin of the wearer and do not become unintentionally unattached during all circumstances of use.

In order to provide the desired level of adhesion of the device to the wearer, the prior art typically discloses the utilisation of certain adhesives having very high cohesive strengths such as rubber based adhesives and acrylics. These adhesives are then applied as thick layers over the entire surface of the flange of the device to maximise the adhesive force by which the device is secured to the skin of the wearer. Indeed it is apparent that these devices and in particular the adhesives have been designed for use on faecal management devices utilised by bedridden patients particularly those having an artificial anus whereby maximum adhesion takes priority over any other criteria such as patient comfort.

However, the adhesive must have a skin compatible composition and not be harsh or aggressive towards the skin or cause skin irritation or inflammation. Also it is preferred if the adhesive is compliant with the skin of the wearer such that maximum skin surface contact between the adhesive and the skin is achieved. Moreover, it is also desirable to provide an adhesive such that the device can be readily removed from the wearer, without the wearer experiencing any unacceptable pain level. This is particularly important under circumstances, where the device is misplaced, and removal and reapplication of the device once or even a number of times is required and or to ensure the application of such devices on sensitive skin and wearer groups such as infants. However, on the other hand the desired level of adhesion, albeit painless should of course also be maintained during such multiple applications of the device.

The problem of the achieving the desired adhesion level is further exacerbated under wet skin conditions. Typically, prior to the placement of the device, the skin is cleaned and is usually as a result moist. The currently available adhesives, such as hydrocolloids, however often do not immediately strongly adhere to the skin and may need to be held in place until sufficient minimum adhesion occurs. Moreover, the overall adhesive ability of such adhesives tends to be significantly reduced on wet skin surfaces per se, so that the device will typically not remain attached to the skin during wearer if any

pressure is exerted onto the device, for example by the movement of the wearer or during the defaecation process.

Moist and wet skin however is not just a problem which is prevalent at the device application stage, as a significant amount of moisture is also generated during the use of the device from the wearer by perspiration and from the material contained in the bag. The resulting humid environment naturally further increases when the device is utilised in combination with a diaper. Under such circumstances current adhesives typically cannot absorb this moisture and again the adhesive strength is reduced to such an extent that the device will often become detached under exertion of pressure during wear. It is hence very important to provide an adhesive which maintains its adhesive strength on wet skin.

None of the prior art in the field of faecal management bags however even recognises or addresses the problem of providing these devices with an adhesive which meets these criteria.

The prior art in the general field of adhesives for attachment to the skin is in contrast more developed in the field of articles such as band-aids, plasters and bandages. These articles are however typically applied in an emergency situation, where for example, a cut into the skin of the wearer has occurred and absorption of the body liquids emanating from a wound is desired. In this context performance aspects of the article such as easy application and use of the product, comfortable wear as well as painless removal, and discreteness are again in subordinate, to other criteria in this case such as sterility, healing support, and mechanical protection of the wound.

WO 97/42985 discloses a wound dressing comprising a layer of absorbent foam material which is coated with a layer of skin adhering hydrophobic gel which have a lower specific adhesivity.

Such adhesives have been disclosed in for example US statutory invention registration H1602 or WO 96/33683 and WO 95/16424. The latter discloses sanitary articles having a topical adhesive which is applied on the wearer facing side of a sanitary napkin along the entire periphery. WO 96/13238 discloses a

topical adhesive which is described in terms of frequency dependency. EP-638 303 discloses the use of a topical adhesive on side cuffs of sanitary napkins in order to keep the cuffs in an upright position. Swiss publication CH-643730 discloses the use of a very long sanitary napkin having chamfered outer edges with a topical adhesive at the four corners of the outer edges in order to provide a topical adhesive area well outside the region of pubic hair growth.

However all of these disclosures typically disclose a product which is designed to be utilised in combination with an undergarment and hence the degree of adhesion actually provided is very low and is not designed to withstand any excessive pressure. Moreover the adhesive is only discussed in general terms or concentrates on the area of application of the adhesive to the article. The nature of adhesive per se other than the basic physical requirements such as pressure sensitivity are not discussed in particular with reference to the chemical composition or the adhesive criteria.

Similarly from the field of urinary management devices it is known, for example from WO 92/11825, to provide a urinary incontinence pad having a resilient body on the exterior surface of which is applied a layer of adhesive such as a hydrophilic hydrogel adhesive.

Hence there still exists a need to provide a disposable absorbent article having an adhesive for the secure attachment and painless removal of the article from the skin of the wearer so as to be suitable for use of sensitive skin and it is thus an object of the present invention to provide such an article.

It is another objective of the present invention to provide an adhesive that exhibits an ability to adhere to skin upon reapplication, particularly multiple reapplication for example when the article is misplaced or maintained, whilst still allowing painless removal. It is yet another objective to provide an adhesive which does not leave residues after removal.

It is yet a further objective of the present invention that the adhesive will adhere to moist or wet skin, independent of whether this is direct application of

the article onto wet skin, or moisture which is generated on the skin surface during the wearing period of the article.

In addition to the above objectives of the present invention it is also desirable for the adhesives to provide additional benefits such as delivery/dispersal of a compound or composition which is beneficial for the skin or for the body in general.

It has now been surprisingly found that the above drawbacks will be substantially alleviated by providing the article with an adhesive as defined hereinafter. The adhesive provides secure attachment, is pleasing to the skin upon application, and yet causes no discomfort upon removal. This is achieved by selecting the characteristics of the adhesive, particularly in terms of the viscous modulus  $G''$  of the topical adhesive and the thickness  $C$  of the layer of adhesive applied to the article.

#### Summary of the Invention

According to the present invention any disposable absorbent article and functional articles as defined herein after which require adhesion to the skin can be provided with an adhesive as defined herein.

The adhesive allows attachment of articles to the skin of the wearer, the adhesive being provided as a layer having a certain thickness or calliper  $C$  measured in millimetres (mm), typically on at least part of the wearer facing surface of the flange.

Detailed analysis of the sequence of common situations occurring from the application of a absorbent article to the time of removal of such articles has shown that specific adhesive characteristics need to be preferably satisfied in order to achieve the desired performance objectives, in particular to secure initial attachment, secure attachment during use and painless removal after wear. The characteristics which have been considered in this context are the elastic modulus describing the elastic behaviour of the material and the viscous modulus which describes the viscous behaviour of the adhesive material.

The viscous behaviour of the adhesive can be interpreted to represent an indication of the ability of the adhesive to quickly attach and securely adhere to a particular surface. The elastic behaviour can be interpreted as an indication of the "hardness" behaviour of the adhesive. Its value is also critical for good initial attachment. Their combination is believed to be an indicator of the required force upon removal. The relation between elastic and viscous modulus is considered to be an indication on which fraction of the removal energy will be dissipated within the adhesive and which fraction is available to trigger the actual removal.

In order to provide adhesives for secure initial and prolonged attachment and easy/painless removal the relation between the elastic modulus and the viscous modulus as well as their dynamic behaviour is also of importance.

The adhesive has an elastic modulus at a temperature of 37°C (100°Fahrenheit) abbreviated  $G'_37$ , a viscous modulus at a temperature of 37°C (100°Fahrenheit) of  $G''_{37}$ , and a viscous modulus at a temperature of 25°C (77°Fahrenheit) of  $G''_{25}$ .

The adhesive according to the present invention preferably satisfies the following conditions;

$G'_37$  (1 rad/sec) is in the range 1500 Pa to 20000 Pa,  
preferably 1500 Pa to 15000 Pa, most  
preferably 3000 Pa to 10000 Pa.

$G''_{37}$  (1 rad/sec) is in the range 100 Pa to 15000 Pa,  
preferably 100 Pa to 10000 Pa, most  
preferably 300 Pa to 5000 Pa.

and the ratio of  $G'_37$  (1 rad/sec) /  $G''_{37}$  (1 rad/sec) is in the range of 1 to 30.

The rheological behaviour can also be related to the values of the Glass Transition Temperature  $T_g$ . For topical adhesives according to the present invention  $T_g$  should preferably be less than -15°C, more preferably less than -20°C and most preferably less than -25°C.

The rheological behaviour and acceptance of a adhesive can also be related to the specific heat capacity. Preferably the specific heat capacity of the adhesive is less than 4 J/g/K, more preferably less than 3 J/g/K and most preferably less than 2 J/g/K.

The rheological behaviour and acceptance of a topical adhesive can also be related to the specific heat conductivity of the adhesive. Preferably the specific heat conductivity is as low as possible, preferably between 1 and 0.1 W/m/K, most preferably between 0.6 and 0.1 W/m/K.

Provided the above rheological conditions are satisfied the adhesives will also satisfy conditions such as sufficient cohesiveness (to prevent residue of adhesive on the skin) which are critical for commercial use of such adhesives and apparent to those skilled in the art. Adhesive compositions which satisfy the above criteria can be used as adhesives for absorbent articles provided they also satisfy the common requirements of being safe for use on human or animal skin during use and generally after disposal of the article.

Often the criteria of hygienic appearance such that adhesive compositions which are transparent or white upon application are preferred.

The above rheological criteria and other considerations can be satisfied by adhesive compositions which are medically suitable substantially water insoluble pressure sensitive adhesives comprising a polymer which forms a 3-dimensional matrix, and comprising less than 10%, preferably less than 5% by weight of said adhesive of hydrocolloids. The polymeric compound or composition is preferably selected from the group consisting of acrylics, sulphonated polymers, vinyl alcohols, vinyl pyrrolidine, polyethylene oxide, or combinations thereof. The adhesive also preferably comprises a plasticiser. The plasticising compound or composition is preferably selected from the group consisting of water, alcohols (preferably glycerol), glycols, polyglycols, or combinations thereof.

According to the present invention, it has been discovered that the relation between the thickness or calliper C, measured in millimetres (mm), of the layer in which the adhesive is provided, typically onto at least a portion of the wearer

facing surface of the flange, and the viscous modulus  $G''_{25}$  at about 100 rad/sec of the topical adhesive, is relevant to the scope of providing an easy and painless removal from the wearer's skin of such a adhesive applied on at least part of the wearer facing surface of an absorbent article for attachment of said article to the skin of a wearer.

The adhesive of the present invention is provided as a layer having a thickness C such that the viscous modulus  $G''_{25}$  (100 rad/sec) and the thickness C satisfy the following empirical equation:

$$G''_{25} \leq [(7.00 + C) \times 3000] \text{ Pa}$$

and preferably also the following empirical equation:

$$G''_{25} \leq [(5.50 + C) \times 1700] \text{ Pa}$$

#### Detailed Description of the Invention

According to the present invention the adhesive can be utilised on disposable absorbent articles such as diapers, sanitary napkins, pantyliners, incontinence devices, perspiration pads and inserts and tampons. In addition the present invention may also find utility to attach other functional and or protective articles to the skin.

The word "skin" according to the present invention does not only relate to the specific derma of the user but includes the mucous tissue as well as the hair which is typically found in the genital region.

The adhesive is provided with the preferred pattern, typically on the wearer facing surface of the article, as a layer having a thickness or calliper C that is preferably constant. The layer can be preferably continuous or alternatively discontinuous, e.g. in form of dots, spirals, or stripes.

Even though adhesives are used like pressure sensitive adhesives on human skin hair and mucous tissues, it is understood that the adhesive compositions could only with difficulty be considered typical pressure sensitive

adhesives (referred to as PSA hereinafter) on the basis of the most characteristic rheological behaviours identifying such materials.

In fact as the person skilled in the art of adhesives knows, the most characteristic feature that distinguishes a PSA from other substances that can temporarily adhere objects (e.g. water between two glass plates could) is the fact that their rheological parameters and especially the Elastic Modulus  $G'$  vary greatly with the frequency of applied stresses. More in particular,  $G'$  of PSA can increase over some orders of magnitude, while the frequency of applied stresses varies from typical bonding frequency to typical debonding frequency, i.e. 1 rad/s to 100 rad/s as indicated below.

As a first consequence, it is therefore inadmissible to define materials intended for use as "adhesives" by giving values of rheological parameters and especially of  $G'$  at a fixed value of frequency. This can be misleading because in the absence of other characteristics it will include materials which have no practical value. It is hence necessary that rheological characterisation must be on the basis of dynamic considerations. This not only applies to the Elastic Modulus  $G'$  but also to the viscous modulus  $G''$  and hence also for  $\tan(\delta) = G''/G'$ .

It is well known that typical PSAs have not only a high variation of  $G'$  across the considered frequencies, but also that there is an even higher variation of  $G''$  which can get close or become even higher than the value of  $G'$ , i.e.  $\tan(\delta)$  becomes about or even greater than 1, in particular at the frequencies that are typical of debonding.

Without wishing to be bound by theory this can be interpreted as meaning that a high fraction of the energy applied for the debonding is dissipated within the adhesive (so it is not effective in causing the debonding) and through the interface of the adhesive and the skin, while this fact causes macroscopically the recording of a very high level of adhesive force.

As indicated above materials useful as adhesives according to the present invention have rheological characteristics which are measured at a reference temperature of 37°C (as usual body temperature of humans) and in a range of frequencies. It has been found that upon application of a disposable absorbent

article with an adhesive, the adhesive contact is formed at a low frequency, while debonding happens at the speed of removing the device. This speed is expressed as a frequency of 100 rad/s, while the low frequency of forming the adhesive bond has been found to be on the order of 1 rad/s. Therefore, the frequency range for use according to the present invention is between 1 and 100 rad/s.

It is believed that the adhesive bonding characteristics are selected most appropriately at human body temperature. Since the adhesive according to the present invention is used directly on skin and the person skilled in the art is directed to select the adhesive composition to have a small specific heat capacity (e.g. preferably less than 4 J/g/K) the actual temperature of the adhesive will reach 37°C very quickly or even be warmed up by a human prior to application.

In order to provide good conditions of bonding, i.e. at a frequency of about 1 rad/sec, the absolute values of the elastic modulus should not be too high, otherwise the adhesive is too hard and it is not able to intimately join or mold to the surface to which it is expected to adhere. It is also important to have a low absolute value of  $G''$  in order to have good cohesion which is particularly valuable for use with absorbent articles while the material remains soft and capable of gently adhering to skin.

The ratio of  $G'_{37}$  (1 rad/sec) over  $G''_{37}$  (1 rad/sec) is important to ensure that these two values are balanced upon adhesion to the skin.

Importantly, the ratio of  $\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$

$G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})$

needs to be large enough to ensure that the dynamic behaviour of both the elastic and the viscous module are maintained in a relationship which provides secure adhesion and painless and easy removal.

Finally the person skilled in the art will also recognise that the Glass Transition Temperature  $T_g$  of the adhesive composition, the specific heat

capacity, and the specific heat conductivity are parameters which are useful to more fully define the group of useful adhesives.

The following set of characteristics should preferably be satisfied for the adhesive of the present invention:

$G'_37$  (1 rad/sec) is in the range 1500 Pa to 20000 Pa, preferably 1500 Pa to 15000 Pa, most preferably 3000 Pa to 10000 Pa.

$G''_{37}$  (1 rad/sec) is in the range 100 Pa to 15000 Pa, preferably 100 Pa to 10000 Pa, most preferably 300 Pa to 5000 Pa.

the ratio of  $G'_37$  (1 rad/sec) /  $G''_{37}$  (1 rad/sec) is in the range of 1 to 30.

the ratio  $\frac{G'_37 (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_37 (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$

is not less than 0.5, preferably in the range 0.7 to 3, most preferably in the range 1 to 1.8.

The value of the ratio  $G'_37/G''_{37}$  at least for the frequency range from above 1 rad/s up to 100 rad/s should preferably be 3.3 or above, more preferably 5 or above, most preferably 10 or above, while not exceeding about 30, preferably 20, anywhere in the frequency interval.

The rheological behaviour can also be related to the values of the Glass Transition Temperature  $T_g$ . For topical adhesives according to the present invention  $T_g$  should preferably be less than  $-15^\circ\text{C}$ , more preferably less than  $-20^\circ\text{C}$  and most preferably less than  $-25^\circ\text{C}$ .

The rheological behaviour and acceptance of a adhesive can also be related to the specific heat capacity. Preferably the specific heat capacity of the

topical adhesive is less than 4 J/g/K, more preferably less than 3 J/g/K and most preferably less than 2 J/g/K.

The rheological behaviour and acceptance of a adhesive can also be related to the specific heat conductivity of the adhesive. Preferably the specific heat conductivity is as low as possible, more preferable between 1 and 0.1 W/m/K, most preferably between 0.6 and 0.1 W/m/K.

In order to provide adhesive compositions which satisfy the requirements of the above rheological and physical characteristics of an adhesive any medically suitable substantially water insoluble pressure sensitive adhesives comprising a polymer which forms a 3-dimensional matrix, and comprising less than 10%, preferably less than 5% by weight of said adhesive of hydrocolloids, meeting the these characteristics may be utilised .

The term hydrocolloid as used herein refers to colloidal absorbent materials, and mixtures of colloidal absorbent materials selected from starch, modified starches such as dextrin, cellulose esters such as carboxymethycellulose, natural gums such as pectin karaya, gelatin, guar gum, gum arabic, locust bean gum, and carboxypolymethylene.

According to the present invention the 3 dimensional matrix also referred to herein as a gel, comprises as an essential component a polymer which can be physically or chemically cross linked. The polymer may be naturally or synthetically derived. The uncrosslinked polymer includes repeating units derived from vinyl alcohols, vinyl ethers and their copolymers, carboxy vinyl monomer, vinyl ester monomers, esters of carboxy vinyl monomers, vinyl amide monomers, hydroxy vinyl monomers, cationic vinyl monomers containing amines or quaternary groups, N-vinyl lactam monomer, polyethylene oxides, polyvinylpyrrolidon (PVP), acrylics such as hydroxyethylmethacrylate, methoxydiethoxyethyl methacrylate and hydroxydiethoxyethyl methacrylate and sulphonated polymers such as acrylamide sulphonated polymers and mixtures thereof. Alternatively, the uncrosslinked polymer may be a homopolymer or copolymer of a polyvinyl ether, or a copolymer derived from half ester of maleic ester. Similarly any other compatible polymer monomer units may be used as

copolymers such as for example polyvinyl alcohol and polyacrylic acid or ethylene and vinyl acetate.

As another alternative, the polymers may be block copolymer thermoplastic elastomers such as ABA block copolymers such as styrene-olefin-styrene block copolymers or ethylene-propylene block copolymers. More preferably such polymers include hydrogenated grade Styrol/Ethylene-Butylene/Styrol (SEBS), Styrene/Isoprene/Styrene (SIS), and Styrol/Ethylene-Propylene/Styrol (SEPS).

Particularly preferred polymers are acrylics, sulphonated polymers such as acrylamide sulphonated polymers, vinyl alcohols, vinyl pyrrolidine, polyethylene oxide and mixtures thereof.

According to the present invention the 3 dimensional adhesive matrix also essentially comprises a plasticiser, which is preferably a liquid at room temperature. This material is selected such that the polymer may be solubilized or dispersed within the plasticiser. For embodiments wherein irradiation cross linking is to be carried out, the plasticiser must also be irradiation cross linking compatible such that it does not inhibit the irradiation cross linking process of the polymer. The plasticiser may be hydrophilic or hydrophobic.

Suitable plasticisers include water, alcohols, polyhydric alcohols such as glycerol and sorbitol, and glycols and ether glycols such as mono- or diethers of polyalkylene glycol, mono- or diester polyalkylene glycols, polyethylene glycols (typically up to a molecular weight of about 600), glycolates, glyceril, sorbitan esters, esters of citric and tartaric acid, imidazoline derived amphoteric surfactants, lactams, amides, polyamides, quaternary ammonium compounds, condensation products of polyethylene imine and epichlorohydrin, liquid polybutenes, esters such phthalates, adipates, stearates, palmitates, sebacates, or myristates, natural or synthetic oils such as vegetable oils, mineral oils, and combinations thereof. Particularly preferred are polyhydric alcohols, polyethylene glycol (with a molecular weight up to about 600), glycerol, sorbitol, water and mixtures thereof.

Typically the adhesive comprises a ratio of polymer to plasticiser by weight of from 1: 100 to 100:1, more preferably from 50:1 to 1:50. However, the exact

amounts and ratios of the polymer and plasticiser will depend to a large extent on the exact nature of polymer and plasticisers utilised and can be readily selected by the skilled person in the art. For example a high molecular weight polymer material will require a greater amount of plasticiser than a low molecular weight polymer.

In addition to the polymer and plasticiser components of the adhesive, the adhesive may comprise a number of optional additional components for example the composition may comprise from 0% to 50% by weight of the composition, of a tackifying resin. Such tackifying resins are particularly useful in combination with ABA block copolymer adhesive compositions. Suitable tackifying resins include for example rosin derivatives, terpene, and terpene-phenolic resins, hydrocarbon resins such as C<sub>5</sub> and C<sub>5</sub>/C<sub>9</sub> resins, aromatic resins and hydrogenated resins.

Other suitable optional ingredients include from 0% to 10 % and more preferably from 0% to 5 % by weight of substances for further facilitating and stabilising the 3-dimensional matrix and the matrix forming process. For example for hydrophobic adhesive compositions these may be fatty acids of C<sub>8</sub> to C<sub>22</sub>, their metallic salts and their polyoxo-derivatives; lanolin derivatives; silica; bentonite, montmorillonite and their derivatives; waxes or mixtures thereof.

Other common additives known in the art such as preservatives, antioxidants, anti UV agents, pigments, mineral fillers and mixtures thereof may also be comprised within the adhesive composition in quantities up to 10% each respectively.

According to the present invention the polymer component of the adhesive can be physically or chemically cross linked in order to form the 3-dimensional matrix. Physical cross linking refers to polymers having cross links which are not chemical covalent bonds but are of a physical nature such that there are areas in the 3-dimensional matrix having high crystallinity or areas having a high glass transition temperature. Chemical cross linking refers to polymers which are linked by chemical bonds. Preferably the polymer is chemically cross linked by radiation techniques such as thermal-, E beam-, UV-, gamma or micro-wave radiation.

In addition when chemical crosslinks are formed in the system, a polyfunctional cross linker and/or a free radical initiator may be present in the premix to initiate the crosslinking upon irradiation. Such an initiator can be present preferably in quantities up to 5% by weight.

The resulting adhesive compositions may be divided into three family types; hydrophilic, hydrophobic and mixed phase compositions dependant upon the nature of the components of the adhesive.

Hydrophilic adhesives are compositions in which typically the plasticiser is water or glycerol or glycol and/or mixtures thereof and the polymeric phase is of synthetic (e.g. polyacrylics). Optionally such compositions may comprise up to 10% by weight of colloid natural gums.

Hydrophobic adhesives are compositions in which the plasticiser is typically an oil or blend of oils of vegetable or mineral origin and the polymer is usually a synthetic polymer, preferably an elastomer, which is soluble or dispersible in such oils.

Mixed phase adhesives are compositions in which both hydrophobic and hydrophilic components, possibly in both plasticisers and polymers, form two or more separate phases. In such cases an emulsifier is preferably present at a suitable level to form stable emulsions between the incompatible phases.

The preferred adhesive compositions for use in the present invention are hydrophilic as these are particularly effective in adhering to wet skin.

Suitable adhesives for use herein include Promeon, available from Promeon Division of Medtronic Inc., Minneapolis Minnesota, USA and hydrogel adhesive available from 3M.

The adhesive is provided, typically on at least a portion of the wearer facing surface of the article, as a layer having a thickness or calliper C that is preferably constant, or that alternatively can vary over the surface interested by the application of the adhesive.

When considering particularly the removal phase of an adhesive composition for attachment to the skin of a wearer, it is commonly recognised that good conditions of removal, i.e. at a frequency of about 100 rad/sec, of the topical adhesive applied to at least part of the wearer facing surface of the flange, are achieved when the adhesive can be easily removed from the skin, and particularly from the bodily hair that are typically located on this area of the skin where the article contacts the body, without causing pain to the wearer, therefore without adhering too hard upon removal, to the skin and the hair of the wearer. Moreover, a good removal implies that the adhesive does not leave residues on the skin or on the hair.

According to the present invention, the relationship between the thickness or calliper C measured in millimetres (mm) of the layer in which the adhesive is provided, typically onto at least part of the wearer's facing surface of the flange of the faecal management device, and the viscous modulus  $G''_{25}$  at 25°C and at about 100 rad/sec of the topical adhesive gives an indication on the painless and easy removal of the adhesive from the skin.

Without being bound to any theory, it is believed that for higher values of  $G''_{25}$  at 100 rad/sec, which overall correspond to a higher adhesiveness of the composition, a thicker calliper or thickness C of the adhesive layer is needed so that the energy applied for the removal is more evenly distributed within the mass of the adhesive, and is therefore transferred smoothly to the skin, so avoiding peaks of energy that typically cause the pain sensation to the wearer. In other words, thinner layers of the adhesive necessitate an adhesive with a lower  $G''_{25}$  at 100 rad/sec to achieve a reduced pain sensation upon removal of the device.

According to the present invention, the adhesive of the present invention provided as a layer having a thickness C measured in millimetres (mm), is such that the viscous modulus  $G''_{25}$  (100 rad/sec) and the thickness C of the adhesive layer satisfy the following empirical equation:

$$G''_{25} \leq [(7.00 + C) \times 3000] \text{ Pa}$$

and preferably the following empirical equation:

$$G''_{25} \leq [(5.50 + C) \times 1700] \text{ Pa}$$

While in a preferred embodiment of the present invention the thickness C of the adhesive layer is constant, such adhesive layer can also have different thicknesses in different portions of the wearer facing surface of the article where it is applied, provided that the above mentioned relationship between C and  $G''_{25}$  is in any case satisfied.

In order to evaluate the effect of the thickness C of the adhesive layer in its relationship with the viscous modulus  $G''_{25}$  (100 rad/sec) of the adhesive of the present invention on the removal of the adhesive used for the attachment of a disposable absorbent article to the skin of a wearer, a Removal Pain Grade Test has been developed. In this test the adhesion of standard substrates, on which the same adhesive has been provided in layers having different thicknesses, on the skin of the forearm of members of a sensory panel is achieved, and upon successive removal the pain is evaluated in terms of pain grade as described herein after.

According to the present invention any disposable absorbent article management device known in the art can be provided with the adhesive according to the present invention.

According to the present invention the adhesive is preferably covered with a release means in order to protect the adhesive, such as siliconized paper. The adhesive can cover the entire wearer facing surface of the article or more preferably have at least one, preferably two to six non-adhesive portions. These portions may be adhesive free or may contain inactivated or covered adhesives. The adhesive is in one preferred embodiment not applied to the entire wearer facing surface area of the article, so as to provide lobes on either side of the article which are non-adhesive and can thereby serve to facilitate placement and removal of the article whilst avoiding contact with the adhesive. These lobes are however preferably also covered by the release means. Before application of the article to the skin of the wearer, the release means if present is removed.

Absorbent articles in which the adhesive according to the present invention can be used, can be made by any of the ways usual in the art. The application of

the adhesive to the wearer facing surface, typically the topsheet surface of an absorbent article should not cause major problems to those skilled in the art since it can be provided by any well known techniques commonly used to apply adhesives. Most preferably the adhesive is provided in a pattern of small incremental areas such as dots or similar.

The adhesive is applied on at least portion of the wearer facing surface of disposable absorbent articles in a layer having a thickness or caliper that is preferably constant, or that alternatively can vary over the surface interested by the application of the adhesive. The adhesive can be applied to the wearer facing surface of the article by any means known in the art such as slot coating, spiral or bead application or printing. Typically the adhesive is applied at a basis weight of from 20g/m<sup>2</sup> to 2500g/m<sup>2</sup>, preferably from 500g/m<sup>2</sup> to 2000g/m<sup>2</sup>, most preferably from 700g/m<sup>2</sup> to 1500g/m<sup>2</sup> depending in the end use envisioned.

If possible, the article also provides breathability by being at least water vapour permeable, preferably air permeable to prevent stuffiness. Breathability, if not supported by the adhesive as such, can be limited to the area of the article where no adhesive is applied.

This invention can be used beneficially on disposable absorbent articles which are applied directly to the skin of a user. The article usually exhibits absorbency for bodily fluids, the protection of the user's garments from soiling, is comfortable to the user, and is easy to produce and to package. The disposable absorbent article is described below by reference to a sanitary napkin or catamenial, however diapers, panty liners, adult incontinence articles, tampons or perspiration pads are also included under the term disposable absorbent articles. The term "sanitary napkin", as used herein, refers to an article which is worn by females adjacent to the pudendal region and which is intended to absorb and contain the various body fluids which are discharged from the body (e.g., vaginal discharges, menses, and/or urine) and which is intended to be discarded after a single use. A disposable absorbent article is preferably thin, more preferably between 1 and 5 mm thick and either substantially flat prior to use or in a preshaped form.

The terms "joined" or "affixed", as used herein, encompasses configurations whereby a first member is directly connected to a second member and configurations whereby a first member is indirectly connected to a second member by connecting the first member to intermediate members which in turn are connected to the second member.

The sanitary napkin has two main surfaces, a body contacting or wearer facing surface on which the adhesive is applied and a garment facing or contacting surface. In a one preferred embodiment a sanitary napkin of the present invention comprises a liquid pervious topsheet, a liquid impervious backsheet joined to the topsheet, and an absorbent core intermediate the topsheet and the backsheet.

The topsheet is compliant, soft feeling, and non-irritating to the wearer's skin. The topsheet also can have elastic characteristics allowing it to be stretched in one or two directions in portions of the topsheet or throughout its extension. Further, the topsheet is fluid pervious permitting fluids (e.g., menses and/or urine) to readily penetrate through its thickness.

Preferred topsheets for use in the present invention are typically selected from high loft nonwoven topsheets and apertured formed film topsheets. Apertured formed films are especially preferred for the topsheets because they are pervious to body exudates and yet non absorbent and have a reduced tendency to allow fluids to pass back through and rewet the wearer's skin. Thus, the surface of the formed film that is in contact with the wearer remains dry, thereby reducing body soiling and creating a more comfortable feel for the wearer. Suitable formed films are described in U.S. Patent 3,929,135; U.S. Patent 4,324,246; U.S. Patent 4,342,314; U.S. Patent 4,463,045; and U.S. Patent 5,006,394. Particularly preferred micro apertured formed film topsheets are disclosed in U.S. Patent 4,609,518 and U.S. Patent 4,629,643. A preferred topsheet for the present invention comprises the formed film described in one or more of the above patents and marketed on sanitary napkins by The Procter & Gamble Company of Cincinnati, Ohio as "DRI-WEAVE".

Adhesives are most suitably used on topsheets having not a homogeneous distribution of liquid passage ways but only a portion of the topsheet comprising

liquid passage ways oriented such that they result in a centrally permeable and peripherally impermeable topsheet for liquids.

Another alternative are so called hybrid topsheets which incorporate fibrous and film like structures particularly useful embodiments of such hybrid topsheets are disclosed in PCT publications WO 93/09744; WO 93/11725 or WO 93/11726.

When referring to the topsheet a multi layer structure or a mono layer structure is contemplated. The hybrid topsheet mentioned above is such a multi layer design but other multi layer topsheets such as primary and secondary topsheet designs are also considered.

The absorbent core also can comprise multiple layers and provides fluid storage and distribution function.

Positioned in fluid communication with, and typically underlying the topsheet is the absorbent core. The core can comprise any usual absorbent material or combinations thereof. It preferably comprises absorbent gelling materials usually referred to as "hydrogel", "superabsorbent", "hydrocolloid" materials in combination with suitable carriers.

Suitable absorbent gelling materials for use herein will most often comprise a substantially water-insoluble, slightly cross-linked, partially neutralised, polymeric gelling material. This material forms a hydrogel upon contact with water. Such polymer materials can be prepared from polymerizable, unsaturated, acid-containing monomers, such as acrylic acid, which are well known in the art.

Suitable carriers include materials which are conventionally utilised in absorbent structures such as natural, modified or synthetic fibers, particularly modified or non-modified cellulose fibers, in the form of fluff and/or tissues. Suitable carriers can be used together with the absorbent gelling material, however, they can also be used alone or in combinations. Most preferred are tissue or tissue laminates in the context of sanitary napkins/pantyliners.

An embodiment of the core, particularly useful in the application of the present invention, comprises a double layer tissue laminate formed by folding the

tissue onto itself. These layers can be joined to each other. Absorbent gelling material or other optional material can be comprised between the layers.

The absorbent core can include optional components normally present in absorbent webs such as odor control agents, in particular suitable zeolites.

The backsheet primarily prevents the exudates absorbed and contained in the absorbent core from wetting articles that contact the absorbent product such as underpants, pants, pyjamas and undergarments. The backsheet is preferably impervious to liquids (e.g. menses and/or urine) and usually manufactured from a thin plastic film.

The backsheet typically extends across the whole of the absorbent core and can extend onto and form part of the topsheet by folding around the absorbent core. Thereby a topsheet configuration as disclosed in US 4,342,314, column 16, lines 47-62 can be achieved without the requirement to selectively aperture the topsheet.

Preferably, the backsheet also provides breathability to the absorbent article by being at least water vapour permeable, preferably air permeable. The backsheet can be a laminate material e.g. of a combination of microporous film and/or non-woven material, and/or apertured formed film. Breathability if desired can be limited to the periphery or the center of the backsheet or it can be across the whole backsheet.

According to the present invention the adhesive may find particular application in diapers. The diaper can be of the conventional type (an embodiment of which is described below although not a limiting example by any means).

As used herein, the term "disposable diapers" refers to articles which absorb and contain body extrudates; and more specifically, refers to articles which are placed against or in proximity to the body of the wearer to absorb and contain the various extrudates discharged from the body and which are intended to be discarded after a single use (i.e., they are not intended to be laundered or otherwise restored or reused) and, preferably, to be recycled, composted or

otherwise disposed of in an environmentally compatible manner. As used herein, the term "diaper" refers to a garment generally worn by infants or incontinence sufferers that is drawn up between the legs and fastened about the waist of the wearer.

A preferred diaper comprises a body portion and a refastenable mechanical fastening device. A preferred body portion comprises a liquid pervious topsheet, and absorbent core, a liquid impervious backsheet, and elastically contractible leg cuffs; each leg cuff preferably comprising a side flap and one or more elastic members. While the topsheet, the absorbent core, the backsheet, the side flaps, and the elastic members may be assembled in a variety of well-known configurations. A preferred disposable diaper configuration is shown and generally described in US 3,860,003, an even more preferred disposable diaper configuration is shown and generally described in WO 93/16669. In this preferred diaper configuration, the backsheet is joined to the topsheet; the absorbent core is positioned between the topsheet and the backsheet; the side flaps extend outwardly from and along each side edge of the absorbent core; and the elastic member is operatively associated with each side flap.

The body portion in the topsheet and the backsheet are coextensive and have length and width dimensions generally larger than those of the absorbent core. The topsheet is superposed on the backsheet thereby forming the periphery of the body portion.

The body portion has an inside surface and an outside surface. When a backsheet is used, it typically forms the outside surface of the body portion. The inside surface is that surface of the diaper opposite the outside surface and in the embodiment shown is typically formed by the topsheet. In general, the inside surface of the diaper is that surface coextensive with the outside surface and which is for the greater part in contact with the wearer when the diaper is worn.

The absorbent core of the body portion may be any absorbent means which is generally compressible, conformable, non-irritating to the skin of the wearer, and capable of absorbing and retaining liquids such as urine and other certain bodily discharges. The absorbent core may be manufactured in a variety of sizes and shapes (for example, rectangular, hour-glass, "T"-shaped, asymmetric, etc.)

and from a wide variety of liquid absorbent materials commonly used in disposable diapers and other absorbent articles such as comminuted wood pulp which is generally referred to as airfelt. Examples of other suitable absorbent materials include creped cellulose wadding, meltblown polymers including coform, crosslinked cellulosic fibers, tissue including tissue wraps, absorbent foams, absorbent sponges, superabsorbent polymers, absorbent gelling materials, or any equivalent materials or combinations of materials. The configuration and construction of the absorbent core may also be varied (for example, the absorbent core may have varying caliper zones, hydrophilic gradients, superabsorbent gradients, or lower average density and lower average basis weight acquisition zones; or may comprise one or more layers or structures). Further, the size and absorbent capacity of the absorbent core may be varied to accommodate wearers ranging from infants to adults.

The backsheet is impervious to liquids (for example, urine) and is preferably manufactured from a thin plastic film, preferably a thermoplastic film, although other flexible liquid impervious materials may also be used. As used herein, the term "flexible" refers to materials which are compliant and which will readily conform to the general shape and contours of the human body. The backsheet prevents the exudates absorbed and contained in the absorbent core from soiling articles which are in contact with the diaper such as undergarments and bedding. The backsheet may thus comprise polymeric films such as thermoplastic films of polyethylene or polypropylene, or composite materials such as film-coated non-woven material. Exemplary films are manufactured by Tredegar Industries, Inc. of Terre Haute, Ind., USA or BP-Chemical PlasTec, Rotbuchenstrasse 1, D-8000 München, Germany.

The backsheet is preferably textured to provide a more clothlike appearance. Further, the backsheet may also permit vapours to escape from the absorbent core while still preventing exudates from passing through the backsheet by, for example, being supplied with microapertures. The size of the backsheet is dictated by the size of the absorbent core (58) and the exact diaper design selected.

The topsheet of the diaper is compliant, soft feeling and non-irritating to the skin of the wearer. Further, the topsheet is liquid pervious permitting liquids (for

example, urine) to readily penetrate through its thickness. A suitable topsheet may be manufactured from a wide range of materials, such as porous foams, reticulated foams, apertured films; or woven or non-woven webs of natural fibres (for example, wood or cotton fibres) or from a combination of natural and synthetic fibres. Preferably, it is made of a material that isolates the skin of the wearer from liquids retained in the absorbent core.

There are a number of manufacturing techniques which may be used to manufacture the topsheet. For example, the topsheet may be a non-woven web of fibres. An exemplary topsheet is carded and thermally bonded by means well-known to those skilled in the fabric art. A suitable topsheet is manufactured by, for example, Veratec Inc., a division of International Paper Company, of Walpole, Mass., USA. A topsheet particularly preferred for incontinence garments comprises a formed thermoplastic film.

According to the present invention the adhesive as described herein may also find application to attach other articles to the skin. The adhesives may for example find utility to adhere functional articles which adhere to the skin such as cosmetic or pharmaceutical delivery articles which provide a substance to the skin such as skin treatment substances, cream, lotions, hormones, vitamins, deodorants, drugs; cosmetic or pharmaceutical delivery articles which provide a substance to emanate away from the skin such as insecticides, inhalation drugs, perfumes and; functional articles which are not necessarily attached to the skin, but which require a high residence time on the skin such as decorative cosmetics, (lipstick, eye shadow, stage make-up) and cleaning articles (hand cleaners, face masks and hygienic pore cleansers). Such articles are preferably non-absorbent for bodily liquids.

The adhesive may also in addition find application to attach articles to the skin such as protective articles such as genital-, knee- or elbow-protectors or bandages; clothing such as bras, surgical gowns, or parts of garments during fitting at a tailor; nasal plasters; prosthesis such as breast replacements or wigs; cold wraps e.g. to provide pain relief from bruises and to reduce swelling; thermal wraps comprising thermal cells as disclosed for example in WO 97/36968 and WO 97/49361 to provide relief of temporary and chronic pain such as neck wraps as disclosed in for example US 5 728 146, knee wraps exemplified in

WO 97/01311, and back wraps as disclosed for example in US 5 741 318; hearing aids; protective face masks (for the reduction or prevention of inhalation of noxious substances); ornamental articles such as jewelry, earrings, guises, tattoos; goggles or other eye wear; ostomy devices, tapes, bandages, dressings of general utility, wound healing and wound management devices; and biomedical skin electrodes such as ECG, EMG, EEG, TENS electrosurgery, defibrillation, EMS and electrodes for facial/beauty applications; and fixation products and/or devices intended to affix patient catheters, tubing leadwires cables etc.

#### Removal Pain Grade Test

The Removal Pain Grade Test is utilized to evaluate the pain during removal from the skin of a wearer of a sample provided with a layer of a adhesive and previously attached to the wearer's skin. The test specifically evaluates the pain upon removal of each sample as compared to the pain obtained by removing a reference sample constituted by a commercial strong medical plaster.

##### Sample preparation.

The test is performed on rectangular samples 60x20 mm made of a polyester film 23  $\mu$ m thick, such as that sold by Effegidi S.p.A. of Colorno (Parma, Italy), provided on one side with a continuous layer of the topical adhesive having the selected thickness, applied with an Acumeter Model LH-1 extruder. The reference sample is a 60x20 mm sample of a of an adhesive non woven fabric available from Beiersdorf A.G. Hamburg, Germany under the Tradename Fixomull stretch.

##### Test method.

A panel of six graders is selected for the test. The test is performed in a climatically controlled laboratory maintained at a temperature of 23 °C and a Relative Humidity of 50%. No special treatment of the wearer's skin is required beyond normal cleaning/washing with water and soap. The skin is then allowed to dry for at least two hours before the test to allow the skin to reach equilibrium with the room conditions. Different adhesive are evaluated in the test in

comparison with the reference sample R. Each sample is applied by hand by an operator to the inner part of the grader's forearm, being centred between the wrist and the elbow, with the short side of the sample aligned with the length of the arm. The operator exerts on each sample with the palm of the hand the same pressure that is typically applied to cause a medical plaster to adhere to the skin. Each sample is worn for the prescribed time, and then it is removed from the grader's skin by the operator with a slow and smooth pull.

Four series of one reference sample R and the test samples are each applied, worn and then removed from the wearer's skin; each sample is worn for one minute, with a 5 minute wait between two subsequent samples of the same series, and a 15 minute wait between two different subsequent series. The reference sample R is always applied, worn and removed as the first sample of its respective series. The sequence of application/wear/removal of the test samples in each of the first three series is random, provided that no repetition in each series is allowed, and that no sequence is repeated in the first three series. In the fourth series one of the test samples is tested twice, the reference R always being the first one. Overall each sample has to be tested an equal number of times (24 times).

The graders were asked to evaluate each sample using a pain scale ranging from 0 to 10, where 0 corresponds to no pain and 10 corresponds to the pain upon removal of the reference sample R. The pain values for each sample were obtained as a mean of 24 observations.

The results collected from the test were analysed by a statistical analysis program "Comparison of Population Means - Paired Samples", that showed that the differences between the pain values of the samples are statistically significant.

**CLAIMS**

1. A disposable absorbent article comprising a wearer facing surface and a garment facing surface, said wearer facing surface comprising at least one portion comprising an adhesive, wherein said adhesive is provided as a layer having a thickness C measured in millimetres (mm),

said adhesive having a viscous modulus at a temperature of 25°C (77°F),  $G''_{25}$ ,

wherein said viscous modulus  $G''_{25}$  (100 rad/sec) and said thickness C of said adhesive satisfy the following equation:

$$G''_{25} \leq [(7.00 + C) \times 3000] \text{ Pa}$$

2. A disposable absorbent article according to claim 1 characterized in that said viscous modulus  $G''_{25}$  (100 rad/sec) and said thickness C satisfy the following equation:

$$G''_{25} \leq [(5.50 + C) \times 1700] \text{ Pa}$$

3. A disposable absorbent article according to claim 1 or 2, characterized in that said adhesive has an elastic modulus at a temperature of 37°C (100°F),  $G'_{37}$ , and having a viscous modulus at a temperature of 37°C (100°F),  $G''_{37}$ , and is selected to have;

a)  $G'_{37}$  (1 rad/sec) in the range 1500 Pa to 20000 Pa, preferably 1500 Pa to 15000 Pa, most preferably 3000 Pa to 10000 Pa;

b)  $G''_{37}$  (1 rad/sec) in the range 100 Pa to 15000 Pa, preferably 100 Pa to 10000 Pa, most preferably 300 Pa to 5000 Pa; and

c) the ratio  $G'_{37}$  (1 rad/sec) /  $G''_{37}$  (1 rad/sec) in the range 1 to 30.

4. A disposable absorbent article according to any one of the preceding claims, wherein said adhesive is a substantially water insoluble pressure sensitive adhesive comprising a polymer which forms a 3-dimensional matrix, and comprising less than 10%, preferably less than 5% by weight of said adhesive of hydrocolloids.
5. A disposable absorbent article according to claim 4, wherein said adhesive comprises a polymer selected from acrylics, sulphonated polymers, vinyl alcohols, vinyl pyrrolidine, polyethylene oxide or mixtures thereof.
6. A disposable absorbent article according claim 4, wherein said adhesive further comprises a plasticiser.
7. A disposable absorbent article according to claim 6, wherein said plasticiser is selected from polyhydric alcohols, polyethylene glycols, sorbitol, water or mixtures thereof
8. A disposable absorbent article according to claim 4, wherein said adhesive is hydrophilic or a hydrophilic-hydrophobic mixed phase adhesive.
9. A disposable absorbent article according to any one of the preceding claims, wherein said wearer facing surface said article comprises at least one non-adhesive portion.
10. A disposable absorbent article according to any one of the preceding claims, characterized in that said adhesive is provided as a continuous layer.
11. A disposable according to any one of the preceding claims, wherein said adhesive is applied to said wearer facing surface by slot coating.
12. A disposable absorbent article according to any one of the preceding claims, wherein said article comprises a topsheet, a backsheet and an absorbent core located inbetween said topsheet and said backsheet.

13. A functional article selected from cosmetic delivery articles, pharmaceutical delivery articles, decorative cosmetic articles, cleaning articles, protective articles, clothing, prosthesis, cold wraps, thermal wraps, having aids, ornamental articles, goggles and eye wear, for attachment to the skin, said article having a wearer facing surface and a garment facing surface wherein said article comprises at least one portion comprising an adhesive wherein said adhesive is provided as a layer having a thickness C measured in millimeters (mm),

said adhesive having a viscous modulus at a temperature of 25°C (77 F),  $G''_{25}$ ,

wherein said viscous modulus  $G''_{25}$  (100 rad/sec) and said thickness C of said adhesive satisfy the following equation:

$$G''_{25} \leq [(7.00 + C) \times 3000] \text{Pa}$$

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61L15/58

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61L A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>°</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 16424 A (KIMBERLY CLARK CO) 22 June 1995 (1995-06-22) cited in the application page 18, line 1 - line 11 figures 1-6 claims 1,3-7,10-17,19,21,23,24,26,27 ---	1-10,12, 13
X	WO 98 25524 A (UROMED CORP) 18 June 1998 (1998-06-18) page 9, line 20 - line 30 claims 1-3,6-8,14,19 ---	1-10,13
X	US 5 695 484 A (COX BRIAN J) 9 December 1997 (1997-12-09) column 3, line 44 - line 51 claims 1,3,4 ---	1-10,13 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

<sup>°</sup> Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

7 October 1999

Date of mailing of the international search report

13/10/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Thornton, S

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 24149 A (MINNESOTA MINING & MFG ;BISCHOF KATHARINA J (DE); KUESTER WILHELM) 10 July 1997 (1997-07-10) comparative example 5 claims 1-12 ---	1-10,13
A	GB 2 115 431 A (VALLEYLAB INC) 7 September 1983 (1983-09-07) figure 1 claims ---	1-10,13
A	WO 91 09633 A (MINNESOTA MINING & MFG) 11 July 1991 (1991-07-11) claims 1-12 ---	1-10,13
A	US 5 559 165 A (PAUL CHARLES W) 24 September 1996 (1996-09-24) example 9 ---	1-8,13
A	US 4 593 053 A (JEVNE ALLAN H ET AL) 3 June 1986 (1986-06-03) column 3, line 26 - line 44 claims ---	1-8,13
A	EP 0 581 581 A (JOHNSON & JOHNSON CONSUMER) 2 February 1994 (1994-02-02) claims 1,3,8-10 -----	1-8,13

## INTERNATIONAL SEARCH REPORT

I: National application No.

PCT/US 99/ 12958

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99 12958

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-3,13 relate to an adhesive composition for a disposable absorbent article defined (inter alia)

by reference to the following parameters:

P1:  $G''25(100 \text{ rad/sec}) = < (7.00 + C) \times 3000 \text{ Pa}$

P2:  $G''25(100 \text{ rad/sec}) = < (5.50 + C) \times 1700 \text{ Pa}$

P3:  $1500 < G'37 (1 \text{ rad/sec}) < 20000 \text{ Pa}$

P4:  $100 < G''37 (1 \text{ rad/sec}) < 15000 \text{ Pa}$

P5:  $G'37 (1 \text{ rad/sec}) / G''37 (1 \text{ rad/sec}) \text{ in the range 1 to 30}$

The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to:

the parts relating to the adhesive composition for a disposable absorbent article mentioned in the description at pages 13-16.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9516424	A 22-06-1995	AU 1402995	A	03-07-1995
		CA 2122660	A	15-06-1995
		FR 2713478	A	16-06-1995
		GB 2284767	A, B	21-06-1995
		ZA 9409971	A	23-08-1995
WO 9825524	A 18-06-1998	AU 1152297	A	03-07-1998
		NO 992877	A	11-08-1999
US 5695484	A 09-12-1997	NONE		
WO 9724149	A 10-07-1997	AU 4743896	A	28-07-1997
GB 2115431	A 07-09-1983	AU 536939	B	31-05-1984
		AU 1058383	A	29-09-1983
		AU 1230288	A	26-05-1988
		CA 1218954	A	10-03-1987
		DE 3305473	A	02-02-1984
		FR 2522006	A	26-08-1983
		JP 1695909	C	28-09-1992
		JP 58162681	A	27-09-1983
		JP 63065235	B	15-12-1988
		JP 1787645	C	10-09-1993
		JP 2211145	A	22-08-1990
		JP 4078310	B	10-12-1992
		US 4699146	A	13-10-1987
		US 4750482	A	14-06-1988
WO 9109633	A 11-07-1991	AT 120967	T	15-04-1995
		AU 648536	B	28-04-1994
		AU 7074791	A	24-07-1991
		CA 2071004	A	29-06-1991
		DE 69018650	D	18-05-1995
		DE 69018650	T	14-12-1995
		DK 507878	T	31-07-1995
		EP 0507878	A	14-10-1992
		ES 2071297	T	16-06-1995
		FI 922986	A	26-06-1992
		HK 91196	A	31-05-1996
		KR 147306	B	01-08-1998
		US 5369155	A	29-11-1994
		US 5270358	A	14-12-1993
US 5559165	A 24-09-1996	AU 702277	B	18-02-1999
		AU 6190696	A	13-02-1997
		CA 2182713	A	09-02-1997
		DE 69601905	D	06-05-1999
		EP 0758009	A	12-02-1997
		ES 2131896	T	01-08-1999
		JP 9125035	A	13-05-1997
US 4593053	A 03-06-1986	CA 1263783	A	05-12-1989
		EP 0184470	A	11-06-1986
		JP 1858892	C	27-07-1994
		JP 5080514	B	09-11-1993
		JP 61179280	A	11-08-1986
EP 0581581	A 02-02-1994	AU 4214193	A	03-02-1994

## Information on patent family members

International Application No

PCT/US 99/12958

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0581581	A	BR 9303024 A	01-03-1994
		CA 2101008 A	30-01-1994
		GR 93100300 A,B	31-03-1994
		JP 6100467 A	12-04-1994
		MX 9304570 A	28-02-1994

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**